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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D LLC, NORTON
(WATERFORD) LTD., and TEVA
PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, AMNEAL IRELAND LIMITED,
AMNEAL PHARMACEUTICALS LLC, and
AMNEAL PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 23-cv-20964-SRC-MAH

**STIPULATION AND ORDER DISMISSING THE PARTIES'
CLAIMS AND DEFENSES REGARDING THE '712 AND '889
PATENTS AND TEVA'S CLAIMS UNDER § 271(e)(2)
REGARDING THE '289, '587, AND '808 PATENTS**

Plaintiffs Teva Branded Pharmaceutical Products R&D LLC, Norton (Waterford) Ltd., and
Teva Pharmaceuticals USA, Inc. (collectively, "Teva" or "Plaintiffs") and Defendants Amneal
Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and

Amneal Pharmaceuticals, Inc. (collectively, “Amneal” or “Defendants”) by their undersigned counsel, hereby stipulate and agree as follows:

WHEREAS, Amneal filed Abbreviated New Drug Application (“ANDA”) No. 211600 with the U.S. Food and Drug Administration (“FDA”) seeking regulatory approval of Amneal’s generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol (“Amneal’s ANDA Product”);

WHEREAS, after receiving Notice of Paragraph IV Certification from Amneal, Teva filed a Complaint (ECF No. 1) asserting that Amneal’s ANDA Product and its use would infringe Teva’s U.S. Patent Nos. 8,132,712 (“the ’712 patent”), 9,463,289 (“the ’289 patent”), 9,808,587 (“the ’587 patent”), 10,561,808 (“the ’808 patent”), 10,695,512 (“the ’512 patent”), and 11,395,889 (“the ’889 patent”) in Civil Action No. 23-cv-20964-SRC-MAH (“this Action”);

WHEREAS, Teva filed a First Amended Complaint (ECF No. 7) asserting that Amneal’s ANDA Product and its use would infringe the ’712 patent, the ’289 patent, the ’587 patent, the ’808 patent, and the ’889 patent;

WHEREAS, Amneal filed its Answer, Affirmative Defenses, and Counterclaims to Plaintiffs’ First Amended Complaint (ECF No. 12) asserting various counterclaims, including declarations of non-infringement and invalidity of the ’712 patent, the ’289 patent, the ’587 patent, the ’808 patent, and the ’889 patent;

WHEREAS, Amneal represents that it has produced ANDA No. 211600 in full and has produced all correspondence with the FDA pertaining to ANDA No. 211600 submitted as of this date and consistent with Local Patent Rule 3.6(j);

WHEREAS, Amneal represents that Amneal's ANDA No. 211600 produced in this Action accurately describes Amneal's ANDA Product, the drug combination product that Amneal seeks to market upon approval of ANDA No. 211600;

WHEREAS, the Court entered an opinion and order (ECF No. 88) mandating that Teva delist the '712 patent, the '289 patent, the '587 patent, the '808 patent, and the '889 patent from the Orange Book in connection with ProAir® HFA;

WHEREAS, the Federal Circuit affirmed the Court's order mandating delisting and denied Teva's petition for rehearing en banc, *see Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, No. 24-1936 (Fed. Cir.), Dkt. 103, 145;

WHEREAS, Teva has sought withdrawal and removal of the '712 patent, the '289 patent, the '587 patent, the '808 patent, and the '889 patent from the Orange Book in connection with New Drug Application No. 021457 under 21 C.F.R. § 314.53(f)(2)(iv) and 21 U.S.C § 355(j)(5)(C)(ii)(I);

WHEREAS, discovery relating to Amneal's antitrust counterclaims was stayed pending resolution of the parties' Fed. R. Civ. P. 12 motions (ECF No. 56 at 1);

WHEREAS, the parties' Rule 12 motions (ECF Nos. 26, 41) concerning the listing of the patents in the Orange Book have been pending in this Court and on appeal, and the deadline for Teva to submit a petition for a Writ of Certiorari from the Supreme Court of the United States is currently July 31, 2025;

WHEREAS, in view of the stay and pendency of the parties' Rule 12 motions, the parties have not engaged in any fact or expert discovery specific to Amneal's antitrust counterclaims;

NOW THEREFORE, Teva and Amneal hereby stipulate and agree, subject to the approval of the Court, as follows:

1. To conserve judicial resources and to avoid the time and expense of further litigation related to Teva's claims for infringement of the '712 patent and the '889 patent, the parties stipulate to dismiss their claims and defenses regarding the '712 patent and the '889 patent:
 - a. Counts I, II, IX, and X of Teva's First Amended Complaint in this Action, C.A. No. 23-cv-20964, ECF No. 7, asserting infringement of the '712 patent and the '889 patent by Amneal in connection with the product that is the subject of ANDA No. 211600;
 - b. Amneal's Third, Fourth, Eleventh, and Twelfth Affirmative Defenses of its Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' First Amended Complaint in this Action, C.A. No. 23-cv-20964, ECF No. 12, asserting that the '712 patent and the '889 patent are not infringed and are invalid;
 - c. Amneal's Counterclaim Counts 11 and 12 of its Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' First Amended Complaint in this Action, C.A. No. 23-cv-20964, ECF No. 12, to the extent asserting that the '712 patent and the '889 patent are not infringed and are invalid.
2. To conserve judicial resources and to avoid the time and expense of further litigation related to Teva's claims for infringement under 35 U.S.C. § 271(e)(2) of the '289 patent, the '587 patent, and the '808 patent, Teva stipulates to the dismissal of:
 - a. Counts III, V, and VII of Teva's First Amended Complaint in this Action, C.A. No. 23-cv-20964, ECF No. 7, asserting infringement of the '289 patent, the '587 patent, and the '808 patent under 35 U.S.C. § 271(e)(2) by Amneal in connection with the product that is the subject of ANDA No. 211600.

3. To conserve judicial and party resources, trial is bifurcated, such that issues of patent infringement and defenses of patent invalidity will be tried first, with the antitrust counterclaims (counts 6-10 in ECF No. 12) being specifically reserved and preserved pending final decision and judgment on the merits of claims and defenses of patent infringement and patent invalidity. Discovery regarding the antitrust counterclaims will continue to be stayed pending final decision and judgment on the merits of patent infringement and patent invalidity.

This Stipulation and Order does not affect any of Teva's other claims for infringement, including Teva's claims for a declaratory judgment of infringement of the '289 patent, the '587 patent, and the '808 patent under 35 U.S.C. §§ 271(a), (b), or (c).

Dated: June 11, 2025

/s/ Liza M. Walsh

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Respectfully submitted,

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SO ORDERED this 12th day of June, 2025

s/ Stanley R. Chesler

Hon. Stanley R. Chesler
United States District Judge